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Eugene Moraz Esq  
Morgan & Finnegan LLP  
345 Park Avenue  
New York, NY 10154

EXAMINER

KAPADIA, MILAN S

ART UNIT

PAPER NUMBER

3626

DATE MAILED: 08/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/579,872

Applicant(s)

ALBRECHT, JEFFREY STEVEN1

Examiner

Milan S Kapadia

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 21-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Notice to Applicant***

1. This communication is in response to the amendment filed 16 June 2003.

Claims 21-39 are pending.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 21-25, 28, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Brown (6,161,095).

(A) As per claim 21, Brown teaches a medical management system comprising:

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a personal communication device programmed to allow a patient to generate a record indicating the patient's decision to self administer a medical treatment (Brown; col. 5, lines 3-34);

a database (Brown; col. 6, lines 48-57);

a network coupling the personal communication device and the database to allow information to pass between the personal communication device and the database (Brown; col. 3, line 63-col. 4, line 6);

wherein, the record generated includes a time the medical treatment was administered and additional information about the medical treatment administered (Brown; col. 5, lines 24-40);

wherein, the personal communication device sends the record to the database over the network (Brown; col. 3, line 63-col. 4, line 6 and col. 5, lines 48-57); and

wherein the record is added to the database (Brown; col. 5, lines 48-57).

(B) As per claim 22, Brown teaches wherein a part of the record is interactively generated by input from the patient and a part of the record is automatically generated by the personal communication device (Brown; col. 5, lines 24-40).

(C) As per claim 23, Brown teaches wherein the database is processed to initiate an automatic medication reorder (Brown; col. 3, lines 3-6 and col. 4, line 43-col. 5, line 14).

(D) As per claims 24 and 25, Brown teaches one or more communications devices

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coupled to the network and programmed to allow healthcare providers and pharmacists to access the database and to communicate with patients (Brown; col. 3, line 63-col. 4, line 34 and col. 7, line 63-col. 8, line 19).

(E) As per claim 28, Brown teaches wherein the database contains patient education material accessible to the patient (Brown; col. 4, lines 46-48 and col. 4, line 57-col. 5, line 23; the examiner interprets “treatment regimen” information as a form of “education material”).

(F) As per claim 31, Brown teaches wherein the database is used to perform tracking and trending of medication administered by the patient (Brown; col. 2, line 66-col. 3, line 3 and col. 6, lines 8-14); the examiner interprets “data collection of facts regarding patient compliance, symptomology, possible drug interactions or side effects of medication, and other facts relevant to evaluation and possible modification of the treatment regimen” as forms of “medication tracking” and interprets “information regarding the entire course of the treatment regimen, such as each updated regimen and its effectiveness...” as forms of “medication or trending.”)

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (6,161,095) as applied to claim 21 above and further in view of Cummings, Jr. (5,301,105).

(A) As per claim 26, Brown fails to expressly teach one or more communications devices coupled to the network and programmed to allow insurance providers to access the database and to communicate with patients. However, this feature is old and well known in the art, as evidenced by Cummings, Jr's teachings with regards to one or more communications devices coupled to the network and programmed to allow insurance providers to access the database and to communicate with patients (Cummings, Jr; abstract and figure 1). It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the system taught by Brown with Cummings Jr's teaching with regards to these limitations, with the motivation of providing patients with predetermined financial support (Cummings, Jr; abstract).

6. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (6,161,095) as applied to claim 21 above and further in view of Goetz et al. (6,421,650).

(A) As per claim 27, Brown fails to expressly teach wherein the patient receives warning messages through the personal communication device indicating that the patient possesses tainted medication. However, this feature is old and well known in the art, as evidenced by Goetz's teachings with regards to this limitation (Goetz; abstract). In particular Goetz teaches determining potential medical interactions with currently prescribed medications (reads on "tainted medication") and alerting the patient to potential interactions between medications and/or provide caution information to the patient for administration of the medication (reads on "patient receives warning messages indicating that the patient possesses tainted medication.") It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the system taught by Brown with Goetz's teaching with regards to this limitation, with the motivation of providing proper information to the patient to get maximum benefit from their medications, tracking medication consumption, and facilitating transfer of critical data for optimal care of the patient (Goetz; col. 2, lines 58-63).

7. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (6,161,095) as applied to claim 21 above and further in view of Halvorson (4,847,764).

(A) As per claim 29, Brown fails to expressly teach the wherein the database

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contains a product catalog. However, this feature is old and well known in the art, as evidenced by Halvorson's teachings with regards to a database that includes a product catalog (Halvorson; col. 36, lines 60-66). It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the system taught by Brown with Halvorson's teaching with regards to this limitation, with the motivation of performing inventory control (Halvorson; abstract).

8. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (6,161,095) as applied to claim 21 above and further in view of Campbell (Campbell, Sandy, "Accordant meets the challenges that rare chronic diseases pose for managed care," Health Care Strategic Management, August 1996).

(A) As per claim 30, Brown teaches that the patient treatment regimen and protocol are stored in a database (Brown; col. 4, lines 43-48), but fails to expressly teach the database is tailored to the disease hemophilia. However, this feature is old and well known in the art, as evidenced by Campbell's teachings with regards to a database consisting of protocols and algorithms for treatments for diseases including hemophilia (Campbell; abstract). It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the system taught by Brown with Campbell's teaching with regards to this limitation, with the motivation of providing treatment regimens and protocols for patients suffering from hemophilia, thereby meeting disease management objectives (Campbell; abstract).



9. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (6,161,095) in view of Goetz et al. (6,421,650) and further in view of Sloane (5,619,991).

(A) As per claim 32, Brown teaches a personal interactive medication logging apparatus comprising:

a processor (Brown; col. 4, lines 35-42);

a memory (Brown; col. 4, lines 35-42);

a communications interface (Brown; col. 4, lines 52-57);

a user interface to receive input from a patient and present information to the patient (Brown; col. 4, lines 35-42);

software stored in the memory and executable on the processor for performing functions comprising:

generating a record in response to patient input received from the user interface, wherein the record indicates the patient's self administration of a medical treatment (Brown; col. 5, lines 24-40) and the time the medical treatment was administered (Brown; col. 5, lines 24-40) and using the communications interface to transmit the record to a central database, outside the personal interactive medication logging apparatus (Brown; col. 5, lines 48-57); and

using the communications interface to receive messages from medical professionals (Brown; col. 3, line 63-col. 4, line 51).

Brown fails to expressly teach using the communications interface to receive messages from the central database comprising warnings. However, this feature is old and well known in the art, as evidenced by Goetz's teachings with regards to this limitation (Goetz; abstract). In particular Goetz teaches alerting the patient to potential interactions between medications and/or provide caution information to the patient for administration of the medication (reads on "messages from the central database comprising warnings"). It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the system taught by Brown with Goetz's teaching with regards to this limitation, with the motivation of providing proper information to the patient to get maximum benefit from their medications, tracking medication consumption, and facilitating transfer of critical data for optimal care of the patient (Goetz; col. 2, lines 58-63).

The combined system of Brown and Goetz collectively teach the record including additional information relevant to monitoring and evaluating the treatment regimen (Brown; col. 5, lines 24-40) but collectively fail to expressly teach wherein the record indicates the patient's symptoms that preceded the medical treatment. However, this feature is old and well known in the art, as evidenced by Sloane's teachings with regards to wherein the record indicates the patient's symptoms that preceded the medical treatment (Sloane; abstract and col. 4, lines 3-9 and col. 4, line 59-col. 5, line 34). It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the collective system taught by Brown and Goetz with Sloane's teaching with regards to this

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limitation, with the motivation of diagnosing the patient's disease or illness (Sloane; col. 1, lines 40-46).

10. Claims 36 and 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (6,161,095) in view of Sloane (5,619,991).

(A) As per claim 36, Brown teaches a personal interactive medication logging apparatus comprising:

a processor (Brown; col. 4, lines 35-42);

a memory (Brown; col. 4, lines 35-42);

a communications interface (Brown; col. 4, lines 52-57);

software stored in the memory and executable on the processor for performing functions comprising:

using the communications interface to receive a medical treatment record indicating a patient's self administration of a medical treatment, the medical treatment record comprising patient identification information, a type of treatment performed, and a time the treatment was performed (Brown; col. 5, lines 24-57);

storing a plurality of received medical treatment records (Brown; col. 5, lines 48-57);

examining the stored medical treatment records to initiate a medication reorder for patients whose supply is running low (Brown; col. 3, lines 3-6 and col. 4, line 43-col. 5, line 14)

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Brown teaches the record including additional information relevant to monitoring and evaluating the treatment regimen (Brown; col. 5, lines 24-40) but fails to expressly teach wherein the record indicates the patient's symptoms that necessitated treatment. However, this feature is old and well known in the art, as evidenced by Sloane's teachings with regards to wherein the record indicates the patient's symptoms that necessitated treatment (Sloane; abstract and col. 4, lines 3-9 and col. 4, line 59-col. 5, line 34). It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the collective system taught by Brown with Sloane's teaching with regards to this limitation, with the motivation of diagnosing the patient's disease or illness (Sloane; col. 1, lines 40-46).

(B) As per claim 39, Brown teaches wherein the medical treatment record further comprises an a response to treatment (Brown; col. 7, line 38-col. 8, line 3) but fails to expressly teach wherein the medical treatment record further comprises an experience that triggered symptoms. However, this feature is old and well known in the art, as evidenced by Sloane's teachings with regards to wherein the record indicates the patient's symptoms that necessitated treatment (Sloane; abstract and col. 4, lines 3-9 and col. 4, line 59-col. 5, line 34). It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the collective system taught by Brown with Sloane's teaching with regards to this limitation, with the motivation of diagnosing the patient's disease or illness (Sloane; col. 1, lines 40-46).

11. Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (6,161,095) and Sloane (5,619,991) as applied to claim 36 above and further in view of Goetz et al. (6,421,650).

(A) Claims 37 and 38 repeat the features of claims 27 and 31, respectively, and are therefore rejected for the same reasons given above in the rejection of claims 27 31 and incorporated herein.

12. Claims 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (6,161,095), Goetz et al. (6,421,650) and Sloane (5,619,991) as applied to claim 32 above and further in view of Glynn (5,774,865).

(A) As per claim 33, the combined system of Brown, Goetz, and Sloan collectively fail to expressly teach a bar code reader and wherein the software is further capable of accepting input from the patient via the user interface to activate the barcode reader and use the information retrieved from the barcode reader to add information to the record comprising the identity of a medication being taken by the patient as part of the medical treatment. However, this feature is old and well known in the art, as evidenced by Glynn's teachings with regards to a bar code reader and wherein the software is further capable of accepting input from the patient via the user interface to activate the barcode reader and use the information retrieved from the barcode reader

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to add information to the record comprising the identity of a medication being taken by the patient as part of the medical treatment (Glynn; abstract and col. 4, lines 32-56). It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the collective system taught by Brown, Goetz, and Sloane with Glynn's teaching with regards to this limitation, with the motivation of monitoring patient compliance (Glynn; abstract).

(B) As per claim 34, the combined system of Brown, Goetz, and Sloan collectively fail to expressly teach wherein the software is further capable of automatically generating part of the record, and presenting the record to the patient for review prior to the record's transmission to the database. However, this feature is old and well known in the art, as evidenced by Glynn's teachings with regards to wherein the software is further capable of automatically generating part of the record, and presenting the record to the patient for review prior to the record's transmission to the database (Glynn; abstract and col. 4, lines 32-56). It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the collective system taught by Brown, Goetz, and Sloane with Glynn's teaching with regards to this limitation, with the motivation of monitoring patient compliance (Glynn; abstract).

(C) As per claim 35, Brown teaches wherein the software is further capable of retrieving patient education material from the database via the communications

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interface (Brown; col. 4, lines 46-48 and col. 4, line 57-col. 5, line 23; the examiner interprets "treatment regimen" information as a form of "education material").

### ***Response to Arguments***

13. Applicant's arguments with respect to new claims 21-39 have been considered but are moot in view of the new ground(s) of rejection.

(A) At pages 6-7 of the 6/16/03 communication, Applicant argues each of the applied references individually. In response, the Examiner respectfully submits that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In particular, the teachings that Applicant argues are missing from the Brown, Halvorson, Campbell, Rindfleisch, Holliday and/or Goetz reference are clearly disclosed in the respective teachings of Sloane, Cummings, Jr and/or Glynn, when considered collectively with that of Brown, Halvorson, Campbell, Rindfleisch, Holliday and/or Goetz, as discussed in detail within a prior Office Action (paper number 10) and in the preceding rejections, and incorporated herein.

Further, the features newly added and entered in the amendment filed 6/16/03, they have been shown to be fully disclosed by or obvious in view of the collective teachings of Brown, Halvorson, Campbell, Rindfleisch, Holliday, Goetz, Sloane,

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Cummings, Jr, and/r Glynn, as discussed above in detail within the preceding sections of the present Office Action.

In addition, it is respectfully submitted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

### ***Conclusion***

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied art teaches a medication dispensing and timing system utilizing patient communicator with internal clock (5,657,236); and a remote health care information input apparatus (5,865,745).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Milan S Kapadia whose telephone number is 703-305-3887. The examiner can normally be reached on Monday through Thursday, 8:30 A.M. to 6:00 P.M. In addition the examiner can be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 703-305-9588. The fax phone numbers for the organization where this application or proceeding is assigned are 703-



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305-7687 for regular communications and 703-305-7687 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.

mf  
mk

August 11, 2003

*Alexander Kacimov*  
ALEXANDER KACIMOV  
AU 3626  
PATENT EXAMINER